

Appl. No. : 10/735,481
Filed : December 12, 2003

REMARKS

Claims 6, 31, 35, 41 and 47 are withdrawn. Claims 37, 43, and 48 are under consideration. Claim 48 has been amended. Support for the amendments can be found in the Specification as filed, for example, in paragraphs [0050] and [0073] and in the Sequence Listing as filed. No new matter has been introduced by these amendments. Applicant understands that upon allowance of the peptide claims, the method claims 31 and 35 may be considered for a rejoinder. Applicant also understands that upon allowance of the generic claim 48 with respect to the elected species of SEQ ID NO: 2, the withdrawn claims 6, 35, 41 and 47 drawn to non-elected species of SEQ ID NO: 3 will be rejoined and considered for patentability. The following addresses the substance of the Final Office Action.

Written description

The Examiner has maintained the rejection of Claims 37, 43 and 48 under 35 USC §112, first paragraph, as failing to comply with the written description requirement. Specifically, the Examiner stated that the Specification must describe at least a substantial number of members of the claimed genus, and that it is not clear what specifically constitutes the C-terminal or where the C-terminal begins and ends internally. The Examiner further stated that the specification is silent as to what amino acids must be present in order for a given fragment to possess the recited antimicrobial activity. “Is the maximum of 50 amino acids contiguous, possess substitutions or deletions?” Claim 48 has been amended to now recite: “An isolated antimicrobially active peptide consisting of a fragment of the C-terminal of dermcidin protein of SEQ ID NO: 1, said fragment consisting of a maximum of 50 and a minimum of 47 contiguous amino acids of said C-terminal, said C-terminal ending at amino acid 110 of SEQ ID NO: 1.” Support for these amendments can be found in the Specification as filed: in Example 4 and the Sequence Listing, the peptide fragment (SEQ ID NO: 3) of dermcidin from its C-terminal is 47 amino acids in length; and in Example 1 and Sequence Listing the dermcidin protein is described as being 110 amino acids in length.

Therefore, as currently amended, Claim 48 covers the genus which includes only 6 species including the two species described in detail in the Specification: SEQ ID NO: 2 (aa 63-109 of dermcidin protein of SEQ ID NO: 1, i.e. 48 contiguous amino acids from the C-terminal of the dermcidin protein, which has a total length of 110 amino acids) and SEQ ID NO: 3 (aa 63-

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110 of dermcidin protein of SEQ ID NO: 1, i.e. 47 contiguous amino acids from the C-terminal of the dermcidin protein). The word "fragment" means a segment or piece of the original, wherein the amino acids are necessarily contiguous, and the claim explicitly spells it out. Therefore, the claimed genus does not include any peptides that possess substitutions or internal deletions of the fragment of the dermcidin protein. The claimed genus includes only 4 additional species: aa 62-110; aa 61-110, aa 61-109 and aa 62-109). Applicant asserts that the currently claimed genus of only 6 species is adequately described by 2 representatives of such small genus. Therefore, Claim 48 is supported by the specification and claims as filed, and its rejection under 35 USC §112, first paragraph should be withdrawn.

Claim objections

The Examiner has objected to Claims 37 and 43 for depending on a higher numbered claim. According to 608.01(j):

"The original numbering of the claims must be preserved throughout the prosecution. When claims are canceled the remaining claims must not be renumbered. When claims are added, they must be numbered by the applicant consecutively beginning with the number next following the highest numbered claim previously presented (whether entered or not). When the application is ready for allowance, the examiner, if necessary, will renumber the claims consecutively in the order in which they appear or in such order as may have been requested by applicant."

Currently, Claim 48 is the first independent claim, with the other claims made dependent on it. Therefore, the applicant will wait for allowance of the claims and which point the examiner, if necessary, may renumber the claims consecutively.

New matter rejection

The Examiner has rejected Claim 48 under 35 USC §112, first paragraph as failing to comply with the written description requirement. Specifically, the Examiner stated that the phrase "comprising a maximum of 50 contiguous amino acids of said C-terminal" does not appear in the specification, or original claims as filed. Applicant respectfully disagrees. Originally filed Claim 2 recites the fragment which comprises a maximum of 50 amino acid residues from the C-terminal region of DCD. The Specification as filed provides 2 examples of such a fragment: SEQ ID NO: 2 and NO: 3, both of which have 48 and 47 contiguous amino acids of the C-terminal of dermcidin protein. Furthermore, the plain meaning of the term "fragment" precludes substitutions or internal deletions (see Merriam Webster's Dictionary

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meaning of a fragment: a part broken off, detached, or incomplete; or Encarta: 1. broken piece: a piece, usually a small piece, broken off something or left when something is shattered; 2. incomplete piece: an incomplete or isolated piece of something). Therefore, even though the phrase does not appear in the specification *verbatim*, the addition of the word “contiguous” in Claim 48 has made explicit what was implicitly present in the Specification as filed. Therefore, Claim 48 is supported by the specification and claims as filed, and its rejection under 35 USC §112, first paragraph should be withdrawn.

If the Examiner believes that word contiguous raises new matter issues, Applicant would be agreeable to removing the word “contiguous”—which is implicit in the meaning of fragment as discussed above.

Definiteness

The Examiner has rejected Claim 48 under 35 USC §112, second paragraph, as being indefinite. Specifically, Claim 48 was found indefinite for reciting the term “contiguous”, because the Specification allegedly does not define the term. Applicant respectfully disagrees. The Specification as filed provides 2 examples of the claimed fragment of the dermcidin protein: SEQ ID NO: 2 and NO: 3, both of which have 48 and 47 contiguous amino acids of the C-terminal of dermcidin protein, respectively. Therefore, even though the word “contiguous” does not appear in the specification *verbatim*, the addition of the word “contiguous” in Claim 48 has merely made explicit what was implicitly present in the Specification as filed.

Additionally, Claim 48 was found indefinite for the use of the phrase “an isolated antimicrobially active peptide consisting of a fragment of the C-terminal of dermcidin protein of SEQ ID NO: 1, said fragment comprising”. Claim 48 has been amended to now recite “consisting” instead of the term “comprising”.

Therefore, currently amended Claim 48 is definite, and its rejection under 35 USC §112, second paragraph should be withdrawn.

As mentioned above, Applicant would be agreeable to removing the word “contiguous” if the Examiner has believes that it raises 112, 1st and 2nd paragraph issues.

Allowable claims

Applicant wishes to thank the Examiner for indicating the Claims 49-51 are allowable.

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CONCLUSION

Applicants have endeavored to address all of the Examiner's concerns as expressed in the outstanding Final Office Action. Accordingly, amendments to the claims, the reasons therefor, and arguments in support of the patentability of the pending claim set are presented above. In light of the above amendments and remarks, reconsideration and withdrawal of the outstanding rejections is specifically requested. If the Examiner finds any remaining impediment to the prompt allowance of these claims that could be clarified with a telephone conference, the Examiner is respectfully requested to initiate the same with the undersigned.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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